K002454

MAR - 7 2001

510(k) SUMMARY

Company Name:	Vital Signs, Inc. 20 Campus Road Totowa, NJ 07512
Contact Telephone Number:	(303) 790-4835, ext. 412
Contact Fax Number:	(303) 799-0210
Official Contact:	Thomas W. Dielmann Vice President RA/QA
Date:	August 7, 2000
Proprietary or Trade Name:	BREAS HA50
Common/Usual Name:	Heated Humidifier
Classification Name:	Respiratory Gas Humidifier (73 BTT) (per 21 CFR 868.5450)
Predicate Device:	Fisher & Paykel Electronics HC100 Humidifier (K915460)

Device Description:

The BREAS HA50 humidifier (figure 2-1) comprises of a heater unit, water container, connection tube, and power cord. The following is a description and function of each of the main components:

- Heater Unit – housing which water container is placed and applies heat via heating plate, which in turn heats the water. The front panel contains the temperature control knob of the heater plate (settings 1-9), mains power switch, AC power socket, and indicator LED's (power on/off and heating). Dimensions = 15 x 17 x 17.5 cm, weight = 0.9 kg, mains voltage = 115/230 V AC, 50-60 Hz.
- Water Container – a sealed cylindrical container with a metal bottom plate and a water capacity of 500 ml. The cover with seal has two 22mm O.D. conical ports, one for air in from the CPAP device/ventilator and the second for air out to the patient. The container is reusable and can be disassembled for cleaning purposes. A maximum fill level indication is present on the outside of the container.
- Connection Tube – the tube is 60 cm in length and connects the CPAP device/ventilator to the humidifier. The tube is reusable and can be cleaned in the same manner as the water container.
- Power Cord – plugs into an ordinary power socket and into the front panel of the heater unit.

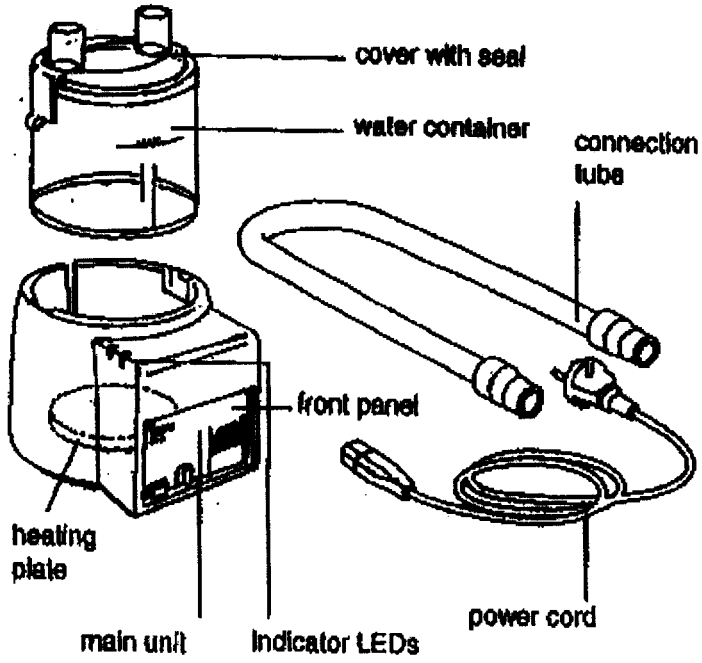

Figure 2 – 1. BREAS HA50 Humidifier

Intended Use:

The BREAS HA50 is a humidifier intended to increase the breathing comfort for patients using various types of ventilators. The HA50 is mainly used in combination with a continuous positive airway pressure (=CPAP) device/ventilator intended for the treatment of obstructive sleep apnea. In normal conditions, the nose and the airways keep the air we breath in, sufficiently humid. In a dry environment or, when using a CPAP device/ventilator, the normal humidification may not be sufficient. When the air you breathe in is too dry, you may suffer from dry airways and from mucus building up, which in turn may cause ache, irritation or infection.

Operating Principle:

The humidifier is placed in between the CPAP device/ventilator and the patient (figure 2-2). Air comes in one port of the water container and flows through the out port to the patient, thereby increasing its humidity as it passes over the water. The heater plate on which the water container is placed, warms the water to increase relative humidity and air temperature delivered to the patient. The maximum air temperature increase caused by the unit is 4°C.

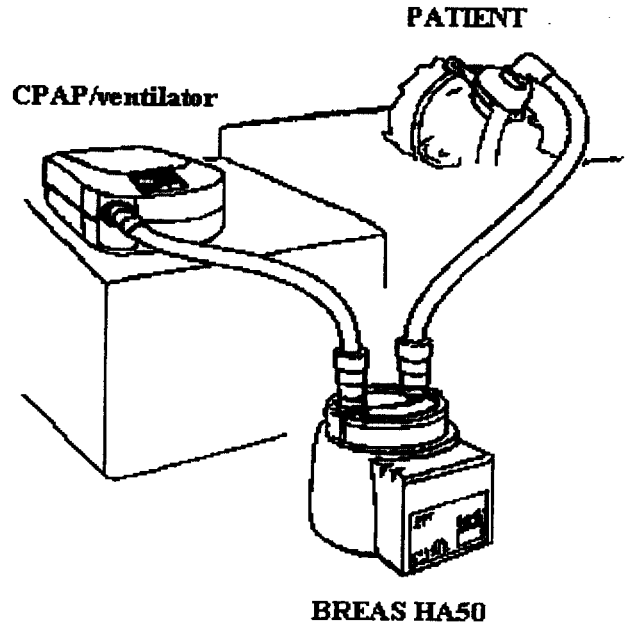

Figure 2 – 2. Humidifier Set-Up

Comparison to Predicate Devices:

The BREAS HA50 Humidifier is substantially equivalent to the F&P HC100 Humidifier (K915460). Both devices increase the humidity of air delivered to a patient and are used in conjunction with CPAP devices/ventilators. There are no significant differences that affect safety or efficacy of the intended device as compared to the predicate devices.

Intended Use	Increase air humidity delivered to the patient. Not for patients whose supraglottic (upper) airways have been bypassed.	Same
Method	Pass-over humidification. Air delivered to patient is through tubes connected to humidifier, air flows through water container. Heater plate used to increase water temperature.	Same
Where Used	Hospital or home healthcare.	Same
Prescription Device	Yes	Yes

510(k) SUMMARY

Temperature Control	Heater plate temperature controlled, device designed to avoid output air temperature greater than 41°C. Delivered air temperature is not measured and indication of temperature not provided.	Same
Humidity Control	Up to 100%RH delivered to patient depending on ambient conditions and air flow rates. Delivered relative humidity is not measured and indication of RH not provided.	Same
Equipment Interface	Connected between patient and CPAP devices/ventilator.	Same
Accessories	Water container, tubes, etc., recommended to be supplied by manufacturer only. Maximum fill indicated on water container to prevent water overflow.	Same
Audio/Visual Alarms	Indicator LED's for power on/off and activated heater plate. Limited temperature delivery, operating conditions specified to avoid output air temperature greater than 41°C.	Same
Physical Configuration	Height = 17 cm Width = 15 cm Length = 17.5 cm Weight = 0.9 kg	Height = 6.5 cm Width = 13.5 cm Length = 15 cm Weight = 0.8 kg
Electrical Safety	Complies with medical electrical safety test specifications.	Same
Materials	Materials commonly used in medical devices with same and/or greater levels of patient contact – Polyethylene(PE), Polystyrene(PS), Polypropylene(PP), ABS, Polycarbonate(PC), Silicone rubber	Same
Reusable	Heating unit, water container and connection tube all reusable. Proper cleaning of water container and connection tube specified.	Same
Labeling	Users manual contains directions for use of the device, specifications, and appropriate cautions/warnings.	Same
Sterilization	Not applicable, supplied clean and non-sterile.	Same

Performance Testing:

The BREAS HA50 Humidifier has been tested and complies with the following FDA **recognized standards**:

Medical Electrical Equipment

IEC 60601-1:1988 including A1: 1991 and A2: 1995 ***Medical Electrical Equipment – Part 1: General requirements for safety.***

IEC 60601-1-1:1992 including A1: 1995 ***Medical Electrical Equipment – Part 1.1: Collateral standard: Safety requirements for medical electrical systems.***

IEC 601-1-2:1993 ***Medical Electrical Equipment – Part 1.2: Collateral standard: Electromagnetic compatibility – Requirements and tests.***
[Included in 601-1-2, required testing was performed for **EMC Emissions** and **EMC Immunity**]

EMC Emissions Test Criteria Applied: conducted emissions 10/150kHz – 30MHz, radiated emissions (magnetic field) 10kHz – 30 MHz, radiated emissions (electric field) 30MHz – 1000MHz, interference power 30MHz – 300MHz, insertion loss 150kHz – 1605kHz, equivalent radiated emission 1GHz – 18GHz, limits for harmonic current emissions (basic document 61000-3-2: 1995), and limitation of voltage fluctuations and flicker (basic document 61000-3-3: 1995).

EMC Immunity Test Criteria Applied: ESD immunity (basic document 61000-4-2), radiated immunity (basic document 61000-4-3), electrical fast transients/burst immunity (basic document 61000-4-4), surge transients immunity (basic document 61000-4-5). Optional testing per latest draft IEC 601-1-2: 1998 was also performed and included conducted immunity (basic document 61000-4-6), power frequency magnetic field (basic document 61000-4-8), and AC dips, interruptions, variations (basic document 61000-4-11).

Respiratory Gas Humidifiers

ISO 5356-1: 1996 ***Anaesthetic and Respiratory Equipment – Conical Connectors.***

In addition to the above FDA recognized standards, the BREAS HA50 Humidifier was tested and complies with the following ISO Standard for the medical devices industry:

ISO 8185: 1997 *Humidifiers for medical use – General Requirements for humidification systems.*

[This standard sets total-system requirements, including accessories such as connection tubes and water containers. This standard contains requirements specific to the safe and effective use of humidifiers – water overflow, air temperature output (max 41°C), humidifier output (min. 10mg/H2O/liter), maximum flow resistance (0.2kPa at 60LPM), and gas leakage (max. 10ml/min at 8kPa)

Conclusion:

In accordance with the Federal Food, drug and Cosmetic Act and 21 CFR Section 807, and based on the information provided in this premarket notification, Vital Signs, Inc. concludes that the device, BREAS HA50 humidifier, is safe, effective and substantially equivalent to the predicate devices as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 7 2001

Mr. Thomas W. Dielmann
Vital Signs, Inc.
c/o Marquest Medical Products, Inc.
11039 East Lansing Circle
Englewood, CO 80112

Re: K002454
Breas HA50 Humidifier, Model HA50
Regulatory Class: II (two)
Product Code: 73 BTT
Dated: March 1, 20001
Received: March 2, 2001

Dear Mr. Dielmann:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish

further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ATTACHMENT A

INDICATION FOR USE STATEMENT

510(k) Number: K002454

Device Name: BREAS HA50 Humidifier

Indications for Use:

The BREAS HA50 is a humidifier intended to humidify gases delivered to a patient with a CPAP device or a bilevel ventilator constructed to use an intentional mask leak and no active exhalation valve.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X or **Over-the-Counter Use**_____
(Per CFR 801.109)

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Division of Cardiovascular & Respi...
510(k) Number K002454